PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: 4435
URI SAGMAN ET AL.	Group Art Unit: 1618
Serial No.: 10/623,110	Examiner: Nabila G. Ebrahim
Filed: July 18, 2003	Attorney Docket: 4451.003200/RFE
For: FULLERENES IN TARGETED THERAPIES	**CUSTOMER NO. 23720**

APPEAL BRIEF

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby submit this Appeal Brief to the Board of Patent Appeals and Interferences in response to the final Office Action dated November 19, 2007.

The Director is authorized to deduct said fee and any additional fees under 37 C.F.R. §§ 1.16 to 1.21 from Williams, Morgan & Amerson, P.C. Deposit Account No. 50-0786/4451.003200RE.

I. REAL PARTY IN INTEREST

The real party in interest is Tego BioSciences, having a place of business at 201 South Lake Ave., Suite 703, Pasadena, CA 91101.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF THE CLAIMS

Claims 2, 5, 11, and 20 have been canceled. Claims 1, 3-4, 6-10, and 12-19 are rejected and are the subject of this appeal.

IV. STATUS OF AMENDMENTS

Applicants did not file any amendments after mailing of the final rejection. Upon recent review, Applicants note that claim 19 erroneously depends on claim 10, when it would properly depend on claim 16. Applicants either will amend claim 19 after it is found otherwise allowable or request the Examiner correct the dependency of claim 19 by an Examiner's amendment.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is directed to a composition comprising (i) a C_n-Ab, wherein C_n is a fullerene or nanotube comprising n carbon atoms, and Ab is a moiety comprising an antigen-binding site and is covalently linked to the C_n, wherein the antigen-binding site recognizes an antigen associated with a medical condition; and (ii) a pharmaceutically-acceptable carrier (p. 3, line 26 to p. 4, line 5; p. 5, lines 17-19; and p. 11, lines 3-9). C_ns are described in the specification at p. 5, line 20 to p. 7, line 13 and Abs are described in the specification at p. 7, line 17 to p. 10, line 23. Exemplary components of the composition are schematically depicted in Figures 1-2. Claim 6 is

directed to the above composition, further comprising a therapeutic molecule associated with the C_n-Ab (p. 11, lines 13-25 and p.13, line 22 to p. 14, line 27). Therapeutic molecules are described in the specification at p. 11, line 16 to p. 13, line 19. Exemplary components of the composition are schematically depicted in Figure 3.

Claim 10 is directed to a method of treating a disease in a mammal comprising administering to the mammal an effective amount of the composition (p. 3, line 26 to p. 4, line 5; p. 5, p. 11, lines 10-15). Claim 16 is directed to the above method, wherein the composition further comprises a therapeutic molecule associated with the C_n-Ab (p. 11, lines 13-25 and p.13, line 22 to p. 14, line 27).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Are claims 1, 3-4, 10, and 12-15 obvious under 35 U.S.C. §103(a) over Erlanger, *et al.*, US 6,593,197 ("Erlanger"), in view of Haberzettl, *Nanotechnology* 13:R9-R13 (2002) ("Haberzettl") and Williams, et al., *Int. J. Radiat. Oncol. Biol. Phys.* 19(3):633-642 (Sept. 1990) ("Williams")?

Are claims 6-9 and 16-19 obvious under 35 U.S.C. §103(a) over Erlanger, in view of Haberzettl and Williams?

VII. ARGUMENT

A. Patentability of claims 1, 3-4, 10, and 12-15 over Erlanger in view of Haberzettl and Williams

Erlanger discloses antibodies specific for a fullerene or a derivative thereof (col. 2, line 15-18). Williams discloses radiolabeled antibodies specific against tumor antigens.

Haberzettl discusses the possible "application of nanotechnology to medicine," speculating that "[a]dvances in both diagnostic tools and the development and administration of therapeutics *may* soon come together for the creation of nanoscale devices known as nanorobots or more simply, nanobots" (p. R9, first column, second paragraph; emphasis added). As should be apparent, Haberzettl is directed to a hypothetical device that neither he nor any other worker has constructed or even shown how to construct.

Haberzettl discusses components a nanobot *might* include as being an architecture or structure to carry a payload, the payload, and targeting mechanisms, among others. Regarding architectures or structures, buckyballs, fullerenes, and nanotubes are mentioned along with dendrimers, nanoparticles, nanocrystals, viruses, and encapsulated cells. Haberzettl states the "hollow internal structure and ability to be functionalized allows [buckyballs, fullerenes, and nanotubes] to carry a payload" (p. R10, second column, "Buckyballs..." paragraph). However, Haberzettl provides no guidance to the person of ordinary skill in the art at least as to how a buckyball, fullerene, or nanotube would carry a payload; how a payload could be incorporated into the hollow internal structure; how a payload could be released from the hollow internal structure; how the buckyball, fullerene, or nanotube could be functionalized; what functionalizations, if any, would render the buckyball, fullerene, or nanotube able to carry a payload; and whether a buckyball, fullerene, or nanotube would be as or more effective than dendrimers or other architectures in the construction of Haberzettl's hypothetical nanobot. Haberzettl's teachings regarding nanobot structure represent a wish, not a predictable, concrete result.

Likewise, Haberzettl teaches that "[t]he *most likely* mechanisms [for targeting a particular tissue or organ] to be employed are based on antigen/antibody interactions or binding of target

molecules to membrane-bound receptors" (paragraph bridging R10-R11, emphasis added). Haberzettl provides no guidance to the person of ordinary skill in the art at least as to how antigen/antibody interactions would be employed to target a particular tissue; how they would be physically incorporated into an architecture; or whether they would be as or more effective than binding of target molecules to membrane-bound receptors or any other technique not listed in Haberzettl. Haberzettl's teachings regarding nanobot targeting represent a wish, not a predictable, concrete result.

In summary, Haberzettl's speculative and hypothetical teachings, ungrounded with any reference to the chemistry of buckyballs, fullerenes, nanotubes, functionalizations thereof, targeting mechanisms, and the combination thereof into useful structures, give the person of ordinary skill in the art no motivation to combine Haberzettl with either or both of Erlanger or Williams.

Even if, considered strictly for the sake of argument, such motivation existed, the combination of Erlanger with Haberzettl and Williams would not meet the requirements of 35 U.S.C. § 103(a). "[I]n a rejection based on 35 U.S.C. 103, the reference teachings must somehow be modified in order to meet the claims. The modification must be one which *would have been obvious to one of ordinary skill in the art at the time the invention was made*." MPEP 706.02, section V, emphasis added. The person of ordinary skill in the art at the time the invention was made (July 24, 2002, the filing date of the provisional application from which the present application claims priority) would not have found any obvious modifications to Haberzettl from the teachings Erlanger or Williams that would have had a reasonable expectation of success. Erlanger's teachings that fullerenes exist is cumulative over the teachings of Haberzettl. Williams's teachings that antibodies exist is cumulative over the teachings of

Haberzettl. Neither of the references provides the person of ordinary skill in the art with sufficient guidance to find the present claims obvious. Although in some circumstances it may be acceptable to support a finding of obviousness on the "obvious to try" rationale (MPEP 2141, section III, paragraph E), this rationale envisions the person of ordinary skill in the art choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success. In contrast, Haberzettl presents a practically infinite number of unidentified and unpredictable solutions, from which success is unexpectable.

For at least these reasons, claims 1, 3-4, 10, and 12-15 are patentable over Erlanger in view of Haberzettl and Williams.

B. Patentability of claims 6-9 and 16-19 over Erlanger in view of Haberzettl and Williams

Erlanger, Williams, and Haberzettl have been discussed above. In addition to the foregoing, Williams discloses methods of using radiolabeled antibodies specific against tumor antigens to treat tumors. In addition to the foregoing, Haberzettl teaches "a currently available therapeutic agent formulated into a nanoarchitecture" (p. R11, first column, section 2.3, second paragraph), but provides no guidance to the person of ordinary skill in the art at least as to whether a therapeutic agent could be formulated into a buckyball, fullerene, or nanotube; even if possible, how a therapeutic agent could be formulated into a buckyball, fullerene, or nanotube; and which nanoarchitectures would be effective for this use. Haberzettl's teachings regarding nanobot payloads represent a wish, not a predictable, concrete result.

In summary, Haberzettl's speculative and hypothetical teachings, ungrounded with any reference to the chemistry of buckyballs, fullerenes, nanotubes, functionalizations thereof,

targeting mechanisms, payloads, and the combination thereof into useful structures, give the person of ordinary skill in the art no motivation to combine Haberzettl with either or both of Erlanger or Williams, for reasons discussed above.

Even if, considered strictly for the sake of argument, such motivation existed, the combination of Erlanger with Haberzettl and Williams would not meet the requirements of 35 U.S.C. § 103(a), also for reasons discussed above.

For at least these reasons, claims 6-9 and 16-19 are patentable over Erlanger in view of Haberzettl and Williams.

VIII. CLAIMS APPENDIX

The claims that are the subject of the present appeal – claims 1, 3-4, 6-10, and 12-19 – are set forth in the attached "Claims Appendix."

IX. EVIDENCE APPENDIX

There is no separate Evidence Appendix for this appeal.

X. RELATING PROCEEDINGS APPENDIX

There is no Related Proceedings Appendix for this appeal.

XI. CONCLUSION

Applicants submit all pending claims are in condition for allowance.

Respectfully submitted,

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April 14, 2008

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AGENT FOR APPLICANTS

CLAIMS APPENDIX

Claim 1. A composition, comprising:

(i) a C_n-Ab, wherein C_n is a fullerene or nanotube comprising n carbon atoms, and Ab is a moiety comprising an antigen-binding site and is covalently linked to the C_n, wherein the antigen-binding site recognizes an antigen associated with a medical condition; and (ii) a pharmaceutically-acceptable carrier.

Claim 3. The composition of claim 1, wherein the C_n is substituted with one or more water-solubilizing groups.

Claim 4. The composition of claim 1, wherein the Ab comprises an antigen-binding site selected from ZME-018, SCFVMEL, dSCFVMEL, GD2, HuM195, herceptin, BACH 250, ML 3-9, C 6.5, or αMMP9.

Claim 6. The composition of claim 1, further comprising a therapeutic molecule associated with the C_n-Ab.

Claim 7. The composition of claim 6, wherein the therapeutic molecule is covalently bound to the C_n.

Claim 8. The composition of claim 6, wherein the C_n is substituted with a polar group and the therapeutic molecule is associated with the polar group.

Claim 9. The composition of claim 6, wherein the therapeutic molecule is paclitaxel, doxorubicin, vincristine, or cisplatin.

Claim 10. A method of treating a disease in a mammal, comprising:

administering to the mammal an effective amount of a composition comprising (i) a C_n-Ab, wherein C_n is a fullerene or nanotube comprising n carbon atoms, and Ab is a moiety comprising an antigen-binding site and is covalently linked to the C_n, wherein the antigen-

binding site recognizes an antigen associated with the disease, and (ii) a pharmaceutically-acceptable carrier.

Claim 12. The method of claim 10, the C_n is substituted with one or more water-solubilizing groups.

Claim 13. The method of claim 10, wherein the Ab comprises an antigen-binding site selected from ZME-018, SCFVMEL, dSCFVMEL, GD2, HuM195, herceptin, BACH 250, ML 3-9, C 6.5, or αMMP9.

Claim 14. The method of claim 10, wherein the disease is an oxidative stress disease.

Claim 15. The method of claim 10, wherein the composition is administered at a dosage of from about 0.001 mg C_n per kg body weight per day to about 1 g C_n per kg body weight per day.

Claim 16. The method of claim 10, wherein the composition further comprises a therapeutic molecule associated with the C_n-Ab.

Claim 17. The method of claim 16, wherein the therapeutic molecule is paclitaxel, doxorubicin, vincristine, or cisplatin.

Claim 18. The method of claim 16, wherein the composition is administered at a dosage of from about 0.001 mg therapeutic molecule per kg body weight per day to about 1 g therapeutic molecule per kg body weight per day.

Claim 19. The method of claim 10, wherein the method further comprises administering an adjuvant to the mammal, wherein the adjuvant dissociates the therapeutic molecule from the C_n-Ab.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.